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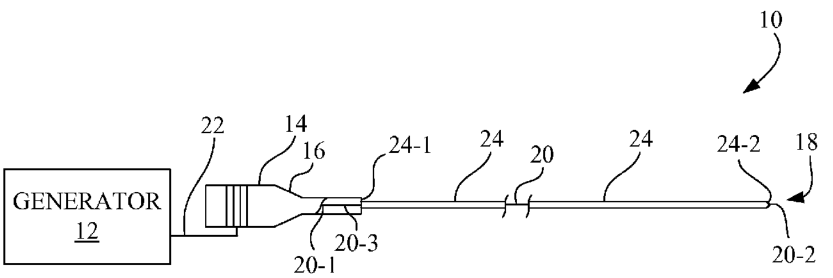

Fig. 1

(57) Abstract: An ultrasound catheter (1() and system (10) includes a catheter sheath (24) having a proximal end (24-1), a distal end (24-2), and a lumen (26) extending between the proximal end (24-1) and the distal end (24-2) in a longitudinal direction. A core wire (20) is movably disposed within the lumen (26) of the catheter sheath (24). The core wire (20) has a proximal portion (20-3) and a distal head portion (30). The proximal portion (20-3) of the core wire (20) is coupled to an ultrasound vibration source (14) configured to transfer the vibration motion to the core wire (20). The core wire (20) is configured to move relative to the catheter sheath (24) to selectively extend and retract the distal head portion (30) of the core wire (20) relative to the distal end (24-2) of the catheter sheath (24) in the longitudinal direction. When the core wire (20) is positioned in an extended position, the head portion (30) of the core wire is free to vibrate in a transverse direction with respect to the longitudinal direction.

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ULTRASOUND CATHETER AND SYSTEM WITH MULTIPLE FUNCTION MODES

Cross-Reference To Related Applications

[0001] This application claims priority to U.S. Provisional Patent Application Serial No. 62/081,857 filed November 19, 2014, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to treatment of blood vessel obstructions, and, more particularly, to an ultrasound catheter and system having multiple vibration modes.

2. Description of the Related Art

[0003] Ultrasound catheter devices may provide disruption of blood vessel obstructions, such as vascular occlusions, as disclosed, for example, in U.S. Patent Application Publication No. 2013/0072824. Generally, an ultrasound transmission member or wire embedded in the body lumen of the catheter transmits vibration energy from a vibration ultrasound transducer to the distal end of the catheter body. The mechanical vibration of the catheter distal end ablates or disrupts the blood vessel obstruction, such as calcific occlusions.

[0004] What is needed in the art is an ultrasound catheter and system having additional capability beyond crossing blood vessel obstructions, such as de-bulking a blood vessel obstruction and enlarging the vessel lumen.

SUMMARY OF THE INVENTION

[0005] The present invention provides an ultrasound catheter and system having additional capabilities beyond crossing blood vessel obstructions, such as de-bulking a blood vessel obstruction and enlarging the vessel lumen.

[0006] The invention, in one form, is directed to an ultrasound catheter for coupling to an ultrasound vibration source. The ultrasound catheter includes a catheter sheath having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction. A core wire is movably disposed within the lumen of the catheter sheath. The core wire has a proximal end portion and a distal head portion.

The proximal end portion of the core wire is arranged for coupling to an ultrasound vibration source configured to transfer vibration motion to the core wire. The core wire is configured for moving relative to the catheter sheath to selectively extend and retract the distal head portion of the core wire relative to the distal end of the elongate cannula in the longitudinal direction, wherein when the core wire is positioned in an extended position, the distal head portion of the core wire is free to vibrate in a transverse motion direction with respect to the longitudinal direction.

[0007] The invention in another form is directed to an ultrasound catheter system, including an ultrasound vibration source configured to generate a vibration motion. An ultrasound catheter has a catheter sheath having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction. A core wire is movably disposed within the lumen of the catheter sheath. The core wire has a proximal portion and a distal head portion. The proximal portion of the core wire is coupled to the ultrasound vibration source. The ultrasound vibration source is configured to transfer the vibration motion to the core wire. The core wire is configured to be moved relative to the catheter sheath to selectively extend and retract the distal head portion of the core wire relative to the distal end of the elongate cannula in the longitudinal direction. When the core wire is positioned in an extended position, the distal head portion of the core wire is free to vibrate in a transverse motion direction with respect to the longitudinal direction.

[0008] The invention in another form is directed to an ultrasound catheter system including an ultrasound catheter, an ultrasound transducer and a transducer driving circuit. The ultrasound catheter includes a catheter sheath and a core wire. The catheter sheath has a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction. The core wire is disposed within the lumen of the catheter sheath. The core wire has a proximal portion and a distal head portion. The ultrasound transducer generates vibration motion. The ultrasound transducer is coupled to the proximal portion of the core wire to transfer the vibration motion to the core wire. A transducer driving circuit is coupled to the ultrasound transducer. The transducer driving circuit is configured to drive the ultrasound transducer with a vibration amplitude that exceeds a buckling strength of the core wire so as to generate transverse motion at the distal head portion of the core wire.

[0009] The invention also relates to an ultrasound catheter for use in such systems as well as an ultrasound transducer and an ultrasound driving circuit for use in such systems. It also relates to an ultrasound vibration source for use in such a system, which can comprise one or both of the ultrasound transducer and the ultrasound driving circuit, as defined in the previous sentence.

[0010] Advantageously, the present invention extends the function of an ultrasound catheter from the function of crossing the blood vessel obstruction to the performance of other procedural functions, such as atherectomy and thrombectomy, by introducing transverse motion vibration at the distal head portion of the ultrasound transmission core wire.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0012] Fig. 1 is a diagrammatic representation of an ultrasound catheter system in accordance with the present invention.

[0013] Fig. 2 is a side section view of a distal portion of the ultrasound catheter of Fig. 1, with the core wire head portion fully retracted against the distal end of the catheter sheath.

[0014] Fig. 3 is a side section view of the distal portion of the ultrasound catheter of Figs. 1 and 2, with the core wire head portion slightly separated distally from the distal end of the catheter sheath.

[0015] Fig. 4 is a side section view of the distal portion of the ultrasound catheter of Figs. 1-3, with the core wire head portion fully extended from the distal end of the catheter sheath.

[0016] Fig. 5 is an end view of the catheter sheath of Fig. 1, showing the distal end of the catheter sheath and the core wire head portion in the fully extended position depicted in Fig. 4.

[0017] Fig. 6 is a block diagram of a transducer driving circuit having a phase locked loop, which may be used in the ultrasound catheter system of Fig. 1.

[0018] Fig. 7 is a block diagram of a transducer driving circuit having frequency sweeping, which may be used in the ultrasound catheter system of Fig. 1.

[0019] Figs. 8A and 8B diagrammatically illustrate an ultrasound catheter system having a handle containing a damping device and a release mechanism to selectively damp transverse vibrations in the core wire.

[0020] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate embodiments of the invention and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION OF THE INVENTION

[0021] Fig. 1 shows an ultrasound catheter system 10 in accordance with the present invention.

[0022] Ultrasound catheter system 10 includes an ultrasound generator 12, an ultrasound transducer 14, an acoustic horn 16, and an ultrasound catheter 18 having a core wire 20. Ultrasound generator 12, ultrasound transducer 14, and acoustic horn 16 form an ultrasound vibration source, which is coupled to core wire 20 of ultrasound catheter 18.

[0023] Ultrasound generator 12 is electrically connected to ultrasound transducer 14 via an electrical cable 22, i.e., a multi-conductor flexible wire cable. Ultrasound transducer 14 is mechanically coupled to acoustic horn 16. As used herein, the term “mechanically coupled” means a physical connection that may be direct (having no intervening structure) or indirect (having intervening structure). Core wire 20 has a proximal end 20-1, a distal tip 20-2, and a proximal end portion 20-3 that extends distally from the proximal end 20-1. Acoustic horn 16 is mechanically coupled to the proximal end 20-1 and the proximal end portion 20-3 of core wire 20.

[0024] Referring also to Figs. 2-4, ultrasound catheter 18 also includes an elongate cannula formed as a catheter sheath 24 having a proximal end 24-1, a distal end 24-2, and a lumen 26. Lumen 26 extends in a longitudinal direction between proximal end 24-1 and distal end 24-2 along a longitudinal axis 27 of catheter sheath 24. Lumen 26 has a diameter D1 for slidably receiving a portion of core wire 20.

[0025] Referring to Figs. 2-5, core wire 20 of ultrasound catheter 18, also sometimes referred to as an ultrasound transmission wire, includes a flexible shaft portion 28, a distal head portion 30, and a neck portion 32. The free distal end of head portion 30 defines the distal tip 20-2 of core wire 20. Flexible shaft portion 28 has a diameter D2 that is smaller than the diameter D1 of lumen 26 of catheter sheath 24 of ultrasound catheter 18. Head portion 30 has a diameter D3 that is larger than the diameter D1 of lumen 26 of catheter sheath 24 of ultrasound catheter 18. In the present embodiment, head portion 30 has an oval shape in profile, and has a circular shape (see Fig. 5) as viewed in a direction into lumen 26 along longitudinal axis 27 toward distal end 24-2 of catheter sheath 24. Neck portion 32 has a diameter D4 that is smaller than the diameter D2 of flexible shaft portion 28.

[0026] Core wire 20 is movably disposed within lumen 26 of catheter sheath, and is movable bi-directionally in lumen 26 of catheter sheath in a longitudinal direction 34 along longitudinal axis 27. Head portion 30 of core wire 20 is movable in longitudinal direction 34 relative to the distal end 24-2 of catheter sheath 24 between a fully retracted position 36, as depicted in Fig. 2, and an extended position 37 and further to a fully extended position 38, as depicted in Fig. 4.

[0027] During a crossing procedure, as in crossing of a chronic total occlusion (CTO) of a blood vessel, core wire 20 is excited to vibrate longitudinally between the positions depicted in Figs. 2 and 3. Fig. 2 depicts head portion 30 of core wire 20 seated, i.e., engaged, with an annular seat 40 defined by the distal end 24-2 of catheter sheath 24. Fig. 3 depicts a position of core wire 20, wherein head portion 30 is slightly separated from annular seat 40. As used herein, the term “slightly separated” is a range of 0.1 millimeters (mm) to 1 mm.

[0028] Referring again to Fig. 1, ultrasound generator 12 generates an electrical excitation signal at a desired frequency, which is supplied to ultrasound transducer 14 via electrical cable 22. Ultrasound transducer 14 responds to the electrical excitation signal by generating a mechanical vibration at a resonant frequency of ultrasound transducer 14. This mechanical vibration is further amplified by acoustic horn 16 and is transmitted into core wire 20 as a mechanical wave. The mechanical wave travels via core wire 20 from the proximal end 20-1 of core wire 20 to the distal tip 20-2 of the distal head portion 30 of core wire 20 to provide a displacement of distal tip 20-2 of head portion 30 in the form of a mechanical vibration. The longitudinal motion component in the mechanical vibration is the major contributor to the crossing of a chronic total occlusion (CTO) of a blood vessel.

[0029] In accordance with the present invention, the vibration at distal tip 20-2 of head portion 30 introduces transverse motion TVM at a level of transverse displacement relative to the longitudinal axis 27 sufficient to de-bulk a blood vessel obstruction, such as calcific occlusion, and enlarge the vessel lumen.

[0030] Referring to Figs. 4 and 5, ultrasound catheter system 10 includes an atherectomy and thrombectomy function mode, wherein ultrasound catheter 18 is configured to vibrate in directions other than longitudinal, i.e., transverse motion TVM in transverse directions at a transverse displacement with respect to the longitudinal direction 34 along longitudinal axis 27. The transverse motion TVM vibrations are effective to ablate or disrupt the blood vessel obstruction surrounding the catheter and enlarge the vessel lumen. Core wire 20 may resonate and form a maximum vibration and a minimum vibration node on core wire 20. The user then may move core wire 20 longitudinally back and forth so that the maximum vibration node of core wire 20 is in contact with all regions containing the blood vessel obstruction.

[0031] Vibration in directions other than longitudinal, i.e., transverse motion TVM, is created when the stress on the core wire exceeds its buckling strength. For example, in the case of the positioning of core wire 20 in Figs. 2 and 3, catheter sheath 24 acts like a transverse wave damping sheath and confines the transverse motion of head portion 30 of core wire 20. However, as depicted in Fig. 4, head portion 30 of core wire 20 is movable in longitudinal direction 34 relative to the distal end 24-2 of catheter sheath 24 between the fully retracted position 36, as depicted in Fig. 2, and the extended position 37 and further to a fully extended position 38, as depicted in Fig. 4.

[0032] The extended position 37 and the fully extended position 38 of head portion 30 of core wire 20 are spaced from distal end 24-2 of catheter sheath 24 a distance in a range from a minimum distance X1 at extended position 37 to a maximum distance X2 at fully extended position 38 to provide for a respective progressive increase in the amount of transverse motion TVM of head portion 30 of core wire 20. Minimum distance X1 is selected to provide a predetermined minimum amount of transverse motion TVM, and maximum distance X2 may be selected as corresponding to the maximum desired amount of the transverse motion TVM. In the present embodiment, minimum distance X1 is 5 millimeters, maximum distance X2 is 150 millimeters, and the range of the transverse motion TVM is 1 micrometer to 50 micrometers. Thus, as the distance is increased from distance X1 to distance X2, a corresponding increase in the amount of transverse motion TVM of the distal head portion 30 of core wire 20 is realized. As depicted in Figs. 4 and 5, the transverse motion TVM that radiates outwardly from longitudinal axis 27 has multiple directional components perpendicular to longitudinal axis 27.

[0033] Thus, in accordance with one embodiment of the present invention, transverse wave motion TVM is created in ultrasound catheter 18 by longitudinally displacing head portion 30 of core wire 20 by a distance in a range of X1 to X2 from distal end 24-2 of catheter sheath 24, so that the transverse motion TVM wave is not constrained by catheter sheath 24. This longitudinal displacement may be effected by moving core wire 20 a selected distance in the range X1 to X2 away from the distal end 24-2 of the catheter sheath 24, or may be effected by retracting catheter sheath 24 relative to core wire 20 a selected distance in the range X1 to X2, so that the transverse wave motion TVM is not constrained by catheter sheath 24, so as to increase the transverse motion TVM of the distal tip 20-2 of head portion 30 of core wire 20.

[0034] Thus, in use, the physician may use ultrasound catheter 18 with head portion 30 of core wire 20 in the condition depicted in Fig. 2 and 3 to ablate or disrupt the blood vessel obstruction. Thereafter, the physician may invoke the atherectomy and thrombectomy mode of ultrasound catheter system 10, wherein in the embodiment depicted in Fig. 4, head portion 30 of core wire 20 is extended distally from the distal end 24-2 of catheter sheath 24 by a distance in a range of X1 to X2, such that the distal head portion 30 of the ultrasound transmitting core wire 20 is longitudinally spaced from the distal end 24-2 of catheter sheath 24 so that head portion 30 of core wire 20 is free to vibrate transversely in the transverse motion TVM. As distance X1 to X2 is increased as head portion 30 of core wire 20 is moved toward the fully extended position 38 of Fig. 4, the amount of transverse displacement of the transverse motion TVM of the head portion 30 of core wire 20 increases.

[0035] In another embodiment, described with further reference to Fig. 6, the creation of vibration of head portion 30 of core wire 20 in a direction other than longitudinal, i.e., transverse direction(s) associated with transverse motion TVM, is effected by driving the ultrasound transducer to increase the stress/vibration amplitude of core wire 20 until the stress/vibration amplitude exceeds the buckling strength of the core wire 20. In this case, the physician may first use ultrasound catheter system 10 to ablate or disrupt the blood vessel obstruction with the ultrasound catheter, as in the condition depicted in Figs. 2 or 3. Thereafter, system parameters of ultrasound catheter system 10, such as the input power, or input frequency, are adjusted so that the stress/vibration amplitude in core wire 20 exceeds its buckling strength limit and creates transverse motion vibration TVM. In the present embodiment, the range of the transverse displacement of the transverse motion TVM with respect to the longitudinal axis 27, i.e., with respect to the longitudinal direction 34, is in a range of 1 micrometer to 50 micrometers, and is dependent upon the amount to which the buckling strength of core wire 20 is exceeded. Fig. 6 shows a transducer driving circuit 50 that may be used in accordance with this embodiment.

[0036] In the circuit configuration of Fig. 6, transducer driving circuit 50 includes a phase locked loop (PLL) circuit 52 including a voltage controller oscillator (VCO) circuit 54, a low pass filter (LPF) circuit 56, and a phase comparator circuit 58. Transducer driving circuit 50 further includes a current sensor circuit (CS) 60, a voltage sensor circuit (VS) 62, an impedance matching circuit (IMC) 64, a temperature sensor circuit 66, a processor circuit 68, a power amplifier circuit 70, and a coupling transformer 72.

[0037] Processor circuit 68 has data processing capability and command generating capability, and in the present embodiment is in the form of a microprocessor having associated non-transitory electronic memory, analog-to-digital circuits (ADC), digital-to-analog circuits (DAC), and input/output (I/O) interface circuitry. The non-transitory electronic memory may include one or more types of electronic memory, such as random access memory (RAM), non-volatile RAM (NVRAM), read only memory (ROM), and/or electrically erasable programmable read-only memory (EEPROM). Processor circuit 68 may be formed as one or more Application Specific Integrated Circuits (ASIC). Processor circuit 68 processes program instructions received from a program source, such as software or firmware, to which processor circuit 68 has electronic access.

[0038] In the circuit configuration of Fig. 6, phase locked loop circuit 52 is used to lock the phase of transducer driving circuit 50. Current sensor circuit 60 senses the motional current of ultrasound transducer 14. Voltage sensor circuit 62 senses the motional voltage of ultrasound transducer 14. The meaning of the term “motional” is that they are the voltage and current after impedance matching by an impedance matching circuit (IMC) 64. Phase comparator circuit 58 receives the motional current and the motional voltage, and extracts the phase of ultrasound transducer 14, which is filtered by low pass filter circuit 56 and is supplied as a voltage input of voltage controlled oscillator circuit 54. Temperature sensor circuit 66 is used to measure the temperature of ultrasound transducer 14.

[0039] Signals that represent the motional current sensed by current sensor circuit 60, the motional voltage sensed by voltage sensor circuit 62, and the temperature sensed by temperature sensor circuit 66, are supplied to processor circuit 68. Processor circuit 68 is configured to process the motional current, motional voltage, and temperature signals, and to provide a control output signal to power amplifier circuit 70. An amplified signal generated by power amplifier circuit 70 is coupled to the impedance matching circuit 64 via a coupling transformer 72. An amount of amplification by power amplifier circuit 70 of the VCS signal generated by voltage controlled oscillator circuit 54 to achieve a transducer driving voltage V supplied to transducer mechanism 14 is dependent on an algorithm executed as program instructions by processor circuit 68, as described below.

[0040] In particular, ultrasound transducer 14 may be driven under different algorithms executed by processor circuit 68, depending upon the desired aspect of the displacement at distal tip 20-2 of head portion 30 of core wire 20 that is to be controlled.

[0041] In one embodiment, an algorithm is executed as program instructions by processor circuit 68 to drive ultrasound transducer 14 in a constant current mode. Driving ultrasound transducer 14 at constant current has the advantage of keeping the same displacement at distal tip 20-2 of head portion 30 of core wire 20 under different tip loading conditions.

[0042] For example, in the constant current mode, processor circuit 68 executes program instructions to generate the transducer driving voltage V supplied to ultrasound transducer 14 by the Equation: $V=\frac{I}{Z}$, where V is the transducer driving voltage, I is an empirically determined constant current setting, and Z is the impedance of ultrasound transducer 14. As used herein, the term “empirically determined” is a value determined through calculation and/or measurements and observation. The value is empirically determined due to variations between similar circuits, i.e., two similar transducer driving circuits 50, such as differences in the physical and/or electrical characteristics of the components used in assembling the circuit.

[0043] In another embodiment, an algorithm is executed as program instructions by processor circuit 68 to drive ultrasound transducer 14 in a constant power mode. Driving ultrasound transducer 14 at constant power has the advantage of keeping the same displacement at distal tip 20-2 of head portion 30 of core wire 20 at different ultrasound transducer temperatures.

[0044] In constant power mode, processor circuit 68 executes program instructions to generate the transducer driving voltage V supplied to ultrasound transducer 14 by the Equation: $V=\frac{P}{Z}$, where V is the transducer driving voltage, P is an empirically determined constant power setting, and Z is the impedance of ultrasound transducer 14.

[0045] In another embodiment, the constant current and constant power modes are combined together as a hybrid algorithm. Using the temperature sensed by temperature sensor circuit 66, the ultrasound transducer 14 is driven so that ultrasound transducer 14 can keep the same or similar displacement at distal tip 20-2 of head portion 30 of core wire 20 with both temperature and tip loading changes.

[0046] In accordance with the hybrid algorithm, a temperature weighting function is introduced into the combined equations. In particular, processor circuit 68 executes program instructions to generate the transducer driving voltage V supplied to ultrasound transducer 14 by the Equation: $V=f(T)\frac{I}{Z} + g(T)\frac{P}{Z}$, where V is the driving voltage, I is an empirically determined constant current setting, P is an empirically determined constant power setting, Z is the impedance of ultrasound transducer 14, f(T) is a temperature weighting function for the constant current aspect and g(T) is a temperature weighting function for the constant power aspect.

[0047] With adjustment of f(T) and g(T), based on empirical data, the algorithm for generating the driving voltage V is designed so that the displacement of distal tip 20-2 of head portion 30 of core wire 20 can be monitored to be the same with tip loading and temperature change.

[0048] Alternatively, as depicted in Fig. 7, a motion sensor circuit 74, such as a displacement sensor, or pressure or stress sensor, may be used as a substitute for temperature sensor circuit 66 and provide feedback to control the power output supplied to ultrasound transducer 14, so that constant tip displacement is monitored.

[0049] Fig. 7 is a transducer driving circuit 80, as an alternative to the circuit of Fig. 6, described above. In the transducer driving circuit 80 of Fig. 7, a frequency generator 82 is used to provide frequency sweeping to track the phase of the motional current and the motional voltage signals supplied by the current sensor circuit 60 and the voltage sensor circuit 62, instead of using the phase locked loop circuit 52 as in the transducer driving circuit 50 of Fig. 6. In the transducer driving circuit 80 of Fig. 7, processor circuit 68 executes program instructions to control frequency generator 82 to sweep the available frequencies to search for the best driving frequency based on the feedback from current sensor circuit 60, voltage sensor circuit 62, and motion sensor circuit 74 as to motional current, motional voltage, and transducer motion (displacement, pressure and/or stress), or alternatively temperature when using a temperature sensor.

[0050] Once the best driving frequency is found, ultrasound transducer 14 is driven by power amplifier circuit 70 via coupling transformer 72 and impedance matching circuit 64 at the determined frequency. The output power from power amplifier circuit 70 also is controlled by processor circuit 68 to maintain a constant current, or constant power, or hybrid of both, as described above, to achieve a constant transverse displacement amplitude at distal tip 20-2 of head portion 30 of core wire 20.

[0051] Referring to Figs. 8A and 8B, in still another embodiment, a handle 90 of ultrasound catheter 18 is coupled to core wire 20 via a damping device 92, such as a plurality (series) of rubber O-rings, and a release mechanism 94. As shown in Fig. 8A, damping device 92 is in a damped position in contact wire core 20 to damp the transverse motion of core wire 20. As shown in Fig. 8B, damping device 92 is in a non-damped position out of contact with wire core 20 to permit the transverse motion TVM of core wire 20. Release mechanism 94 is configured to move dampening device 92 between the damped position and the non-damped position. To achieve the non-damped position, release mechanism 94 removes damping device 92 from contact with wire core 20 so as to release the damping and to facilitate generation of the transverse motion TVM of core wire 20 relative to the longitudinal axis 27.

[0052] Release mechanism 94 may be configured as a solenoid, or mechanical lever or screw, having a movable carriage 96, wherein the carriage 96 is in contact with damping device 92 to selectively move damping device 92 from the damping contact position as depicted in Fig. 8A to the non-damped position of Fig. 8B wherein damping device 92 is spread, e.g., the rubber O-rings are stretched or otherwise distorted, so as to be removed from contact with core wire 20.

[0053] In operation, after the physician performs crossing of the CTO wherein transverse vibration of core wire 20 is suppressed, release mechanism 94 is actuated to release the constraint on core wire 20 provided by damping device 92 and allow the transverse motion TVM wave to be transmitted to distal tip 20-2 of head portion 30 of core wire 20.

[0054] It is contemplated that the damping/release mode may be used in combination with any of the other embodiments/modes previously described herein. Also, it is contemplated that either of the transducer driving circuits described above with respect to Figs. 6 and 7 may be used in combination with the embodiment of Figs. 1-5 in driving ultrasound transducer 14 of Fig. 1.

[0055] In view of the above, those skilled in the art will recognize that the present invention extends the function of an ultrasound catheter from crossing the blood vessel obstruction, to atherectomy and thrombectomy, by introducing more vibration in the transverse direction of the catheter, in the manners as described above.

[0056] While this invention has been described with respect to at least one embodiment, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

WHAT IS CLAIMED IS:

1. An ultrasound catheter for coupling to an ultrasound vibration source, the ultrasound catheter, comprising:

a catheter sheath having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction; and

a core wire movably disposed within the lumen of the catheter sheath, the core wire having a proximal end portion and a distal head portion, the proximal end portion of the core wire being arranged for coupling to an ultrasound vibration source configured to transfer vibration motion to the core wire,

the core wire configured for moving relative to the catheter sheath to selectively extend and retract the distal head portion of the core wire relative to the distal end of the elongate cannula in the longitudinal direction, wherein when the core wire is positioned in an extended position, the distal head portion of the core wire is free to vibrate in a transverse motion direction with respect to the longitudinal direction.

2. The ultrasound catheter according to claim 1, wherein:

the lumen of the catheter sheath has a first diameter; and

the core wire includes a flexible shaft portion, the distal head portion, and a neck portion between the flexible shaft portion and the distal head portion, a free distal end of the distal head portion defining a distal tip of the core wire, and wherein the flexible shaft portion has a second diameter that is smaller than the first diameter of the lumen of the catheter sheath, the distal head portion has a third diameter that is larger than the first diameter of the lumen of the catheter sheath, and the neck portion has a fourth diameter that is smaller than the second diameter of the flexible shaft portion.

3. The ultrasound catheter according to claim 1 or 2, wherein at the distance in the range of 5 millimeters to 150 millimeters, the distal head portion has a corresponding range of transverse motion of 1 micrometer to 50 micrometers.

4. An ultrasound vibration source configured to generate a vibration motion, the ultrasound vibration source being arranged for being used with the ultrasound catheter according to one of the preceding claims.

5. Ultrasound vibration source according to claim 4, wherein to achieve a desired transverse motion of the distal head portion, the distal head portion is moved away from the distal end of the catheter sheath to an extended position, the extended position being selectable in a range of 5 millimeters to 150 millimeters from the distal end of the catheter sheath.

6. Ultrasound vibration source according to one of claims 4 and 5, comprising:

a damping device movable between a damped position in contact with the core wire and a non-damped position out of contact with the core wire; and

a release mechanism configured to move the dampening device between the damped position and the non-damped position, wherein in the non-damped position, the damping device is not in contact with the wire core to facilitate generation of the transverse motion of the core wire relative to the longitudinal direction.

7. Ultrasound vibration source according to claim 6, wherein the damping device is a series of rubber O-rings.

8. Ultrasound vibration source according to claim 6 or 7, wherein the release mechanism is a solenoid having a movable carriage in contact with the damping device to selectively move the damping device from the damped position to the non-damped position.

9. An ultrasound catheter system, comprising:

an ultrasound vibration source according to one of claims 4 to 8 configured to generate a vibration motion; and

the ultrasound catheter according to one of claims 1 to 3 that is coupled to the ultrasound vibration source.

10. An ultrasound catheter system, comprising:

an ultrasound catheter including a catheter sheath and a core wire, the catheter sheath having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction, the core wire being disposed within the lumen of the catheter sheath, the core wire having a proximal end portion and a distal head portion, the ultrasound catheter preferably being an ultrasound catheter according to one of claim 1 to 3;

an ultrasound transducer that generates vibration motion, the ultrasound transducer being coupled to the proximal end portion of the core wire to transfer the vibration motion to the core wire, the ultrasound transducer preferably being comprised by the ultrasound vibration source according to one of claims 4 to 8; and

a transducer driving circuit coupled to the ultrasound transducer, the transducer driving circuit configured to drive the ultrasound transducer with a vibration amplitude that exceeds a buckling strength of the core wire so as to generate transverse motion at the distal head portion of the core wire.

11. The ultrasound catheter system according to claim 10, wherein the transducer driving circuit is configured to drive the ultrasound transducer at constant current so as to keep the same transverse displacement at a distal tip of the distal head portion of the core wire under different tip loading conditions.

12. The ultrasound catheter system according to claim 10 or 11, wherein the transducer driving circuit is configured to drive the ultrasound transducer at constant power so as to keep the same transverse displacement at a distal tip of the distal head portion of the core wire under different temperatures of the ultrasound transducer.

13. The ultrasound catheter system according to one of claim 10 to 12, wherein the transducer driving circuit is configured to drive the ultrasound transducer at both a constant current and a constant power so as to keep the same transverse displacement at a distal tip of the distal head portion of the core wire under different tip loading conditions and under different temperatures of the ultrasound transducer.

14. The ultrasound catheter system according to any of claims 10 to 13, wherein the distal head portion has a range of transverse displacement of the transverse motion of 1 micrometer to 50 micrometers.

15. An ultrasound catheter system, comprising:

an ultrasound vibration source configured to generate a vibration motion; and

an ultrasound catheter coupled to the ultrasound vibration source, the ultrasound catheter including:

a catheter sheath having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction;

a core wire movably disposed within the lumen of the catheter sheath, the core wire having a proximal end portion and a distal head portion, the proximal end portion of the core wire being coupled to the ultrasound vibration source, the ultrasound vibration source configured to transfer the vibration motion to the core wire;

the core wire configured to be moved relative to the catheter sheath to selectively extend and retract the distal head portion of the core wire relative to the distal end of the elongate cannula in the longitudinal direction, wherein when the core wire is positioned in an extended position, the distal head portion of the core wire is free to vibrate in a transverse motion direction with respect to the longitudinal direction.

16. The ultrasound catheter system according to claim 15, wherein to achieve a desire transverse motion of the distal head portion, the distal head portion is moved away from the distal end of the catheter sheath to an extended position, the extended position being selectable in a range of 5 millimeters to 150 millimeters from the distal end of the catheter sheath.

17. The ultrasound catheter system according to claim 16, wherein at the distance in the range of 5 millimeters to 150 millimeters, the distal head portion has a corresponding range of transverse motion of 1 micrometer to 50 micrometers.

18. The ultrasound catheter system according to any of claims 15 to 17, wherein:

the lumen of the catheter sheath has a first diameter; and

the core wire includes a flexible shaft portion, the distal head portion, and a neck portion between the flexible shaft portion and the distal head portion, a free distal end of the distal head portion defining a distal tip of the core wire, and wherein the flexible shaft portion has a second diameter that is smaller than the first diameter of the lumen of the catheter sheath, the distal head portion has a third diameter that is larger than the first diameter of the lumen of the catheter sheath, and the neck portion has a fourth diameter that is smaller than the second diameter of the flexible shaft portion.

19. The ultrasound catheter system of claim 15, characterized by:

a damping device movable between a damped position in contact with the core wire and a non-damped position out of contact with the core wire; and

a release mechanism configured to move the dampening device between the damped position and the non-damped position, wherein in the non-damped position, the damping device is not in contact with the wire core to facilitate generation of the transverse motion of the core wire relative to the longitudinal direction.

20. The ultrasound catheter system according to claim 19, wherein the damping device is a series of rubber O-rings.

21. The ultrasound catheter system according to claims 19 or 20, wherein the release mechanism is a solenoid having a movable carriage in contact with the damping device to selectively move the damping device from the damped position to the non-damped position.

22. An ultrasound catheter system, comprising:

an ultrasound catheter including a catheter sheath and a core wire, the catheter sheath having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end in a longitudinal direction, the core wire being disposed within the lumen of the catheter sheath, the core wire having a proximal end portion and a distal head portion;

an ultrasound transducer that generates vibration motion, the ultrasound transducer being coupled to the proximal end portion of the core wire to transfer the vibration motion to the core wire; and a transducer driving circuit coupled to the ultrasound transducer, the transducer driving circuit configured to drive the ultrasound transducer with a vibration amplitude that exceeds a buckling strength of the core wire so as to generate transverse motion at the distal head portion of the core wire.

23. The ultrasound catheter system according to claim 22, wherein the transducer driving circuit is configured to drive the ultrasound transducer at constant current so as to keep the same transverse displacement at a distal tip of the distal head portion of the core wire under different tip loading conditions.

24. The ultrasound catheter system according to claim 22, wherein the transducer driving circuit is configured to drive the ultrasound transducer at constant power so as to keep the same transverse displacement at a distal tip of the distal head portion of the core wire under different temperatures of the ultrasound transducer.

25. The ultrasound catheter system according to claim 22, wherein the transducer driving circuit is configured to drive the ultrasound transducer at both a constant current and a constant power so as to keep the same transverse displacement at a distal tip of the distal head portion of the core wire under different tip loading conditions and under different temperatures of the ultrasound transducer.

26. The ultrasound catheter system according to any of claims 22 to 25, wherein the distal head portion has a range of transverse displacement of the transverse motion of 1 micrometer to 50 micrometers.

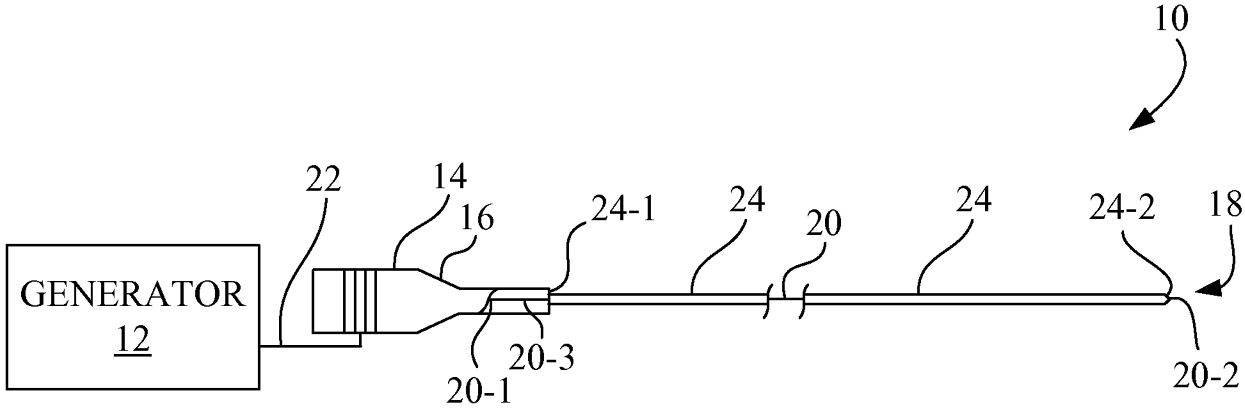


Fig. 1

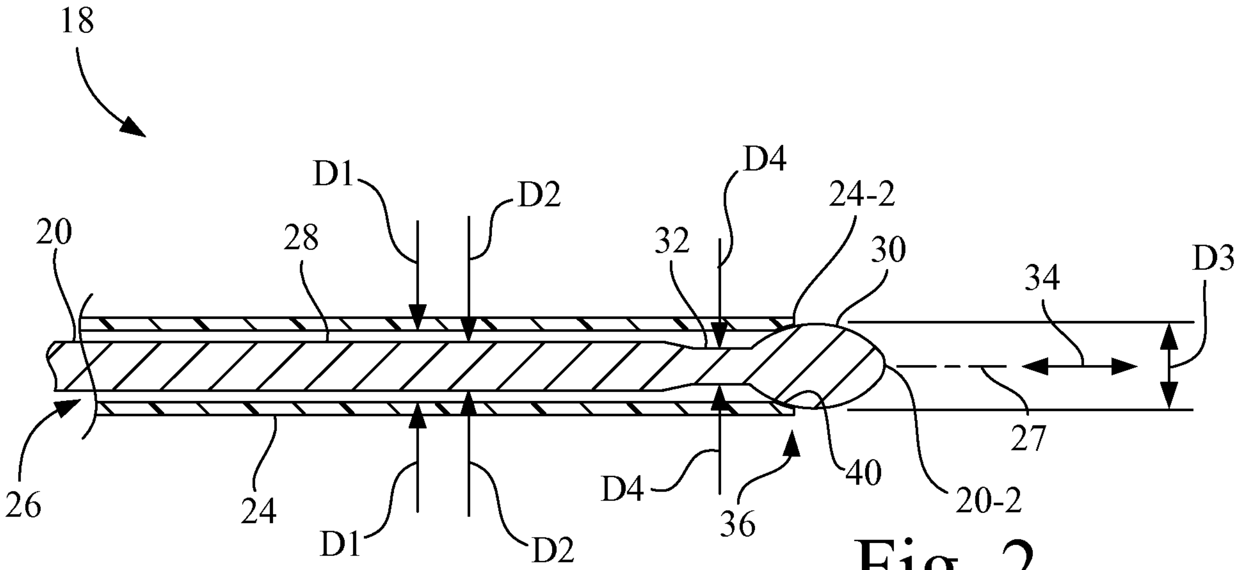


Fig. 2

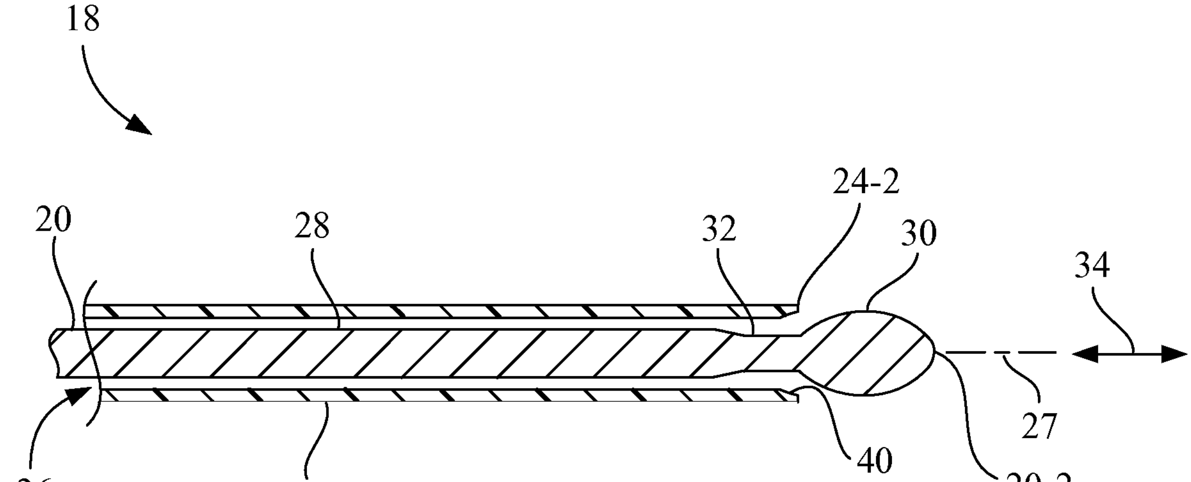
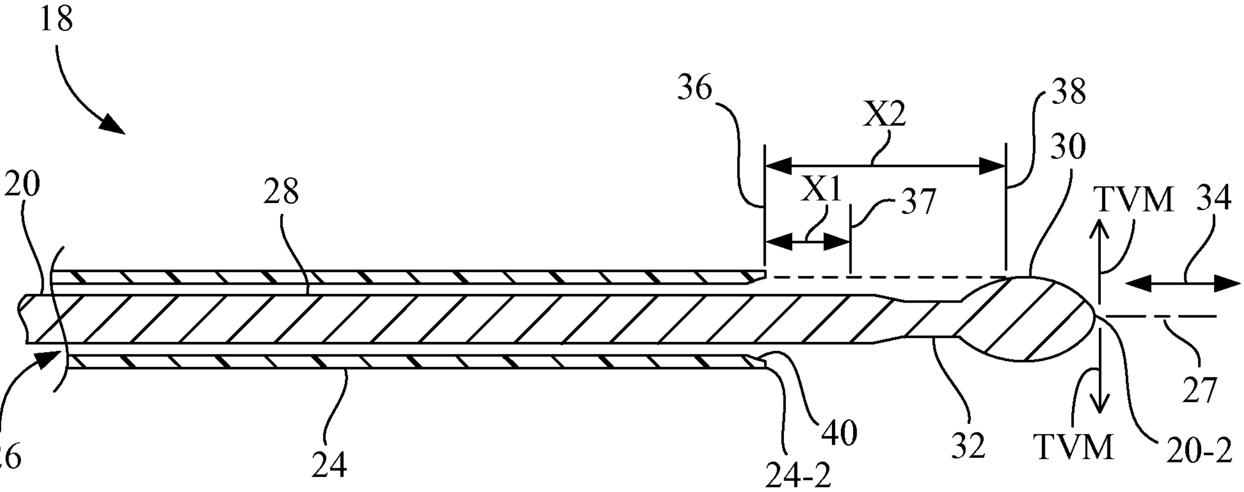


Fig. 3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36
X2
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X1
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TVM
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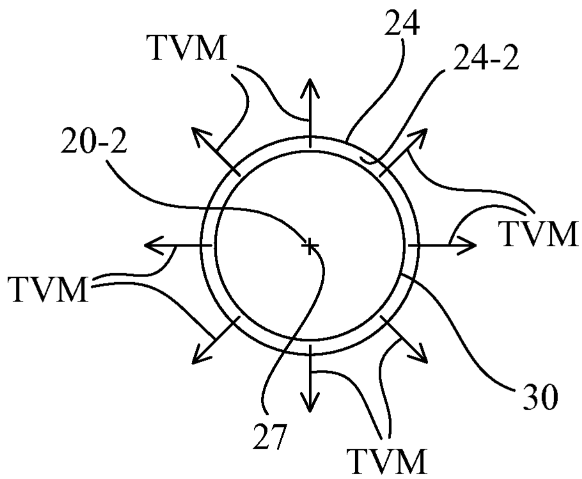
TVM
20-2

Fig. 4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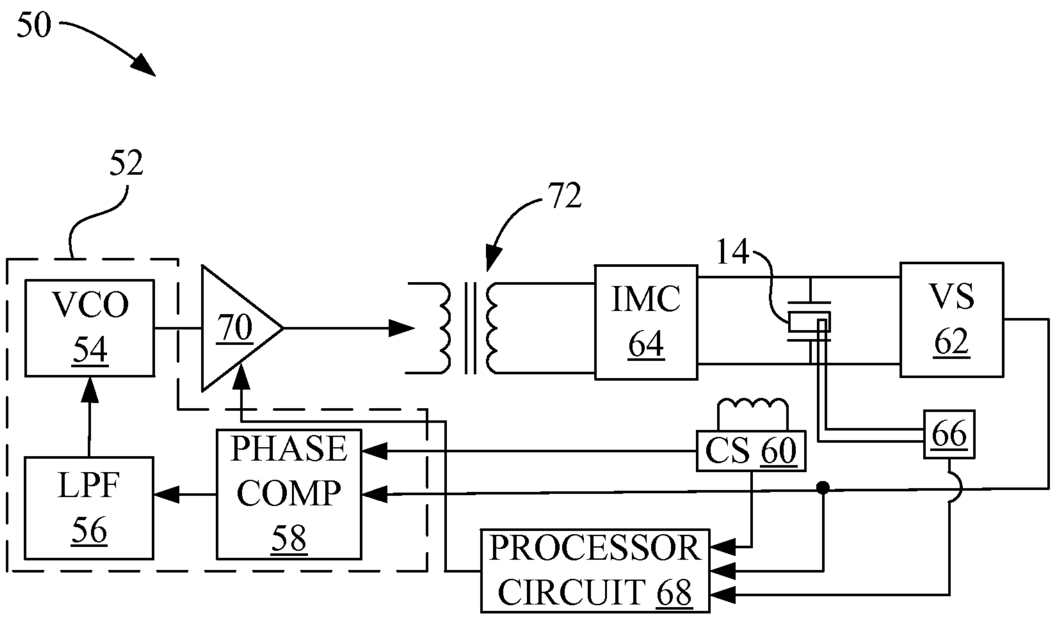
TVM

Fig. 5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LPF
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CS 60
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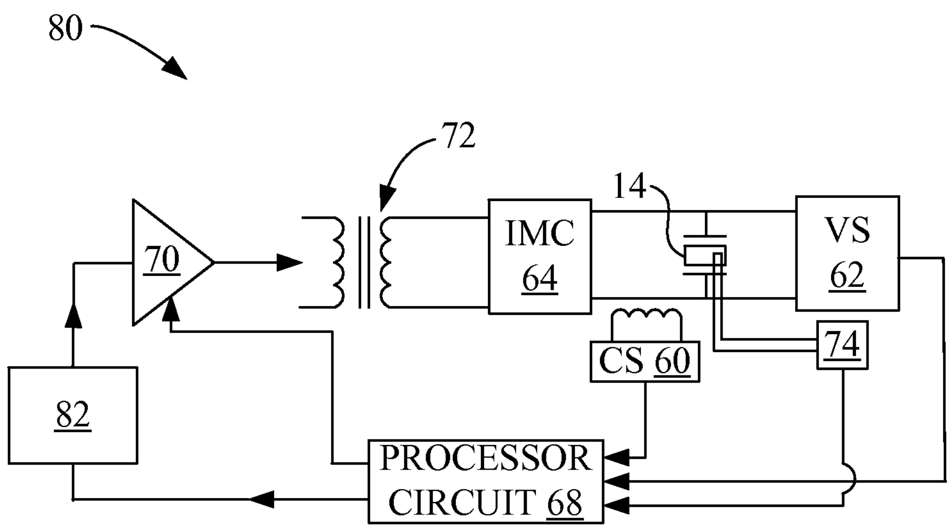
PROCESSOR
CIRCUIT 68

Fig. 6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PROCESSOR
CIRCUIT 68

Fig. 7

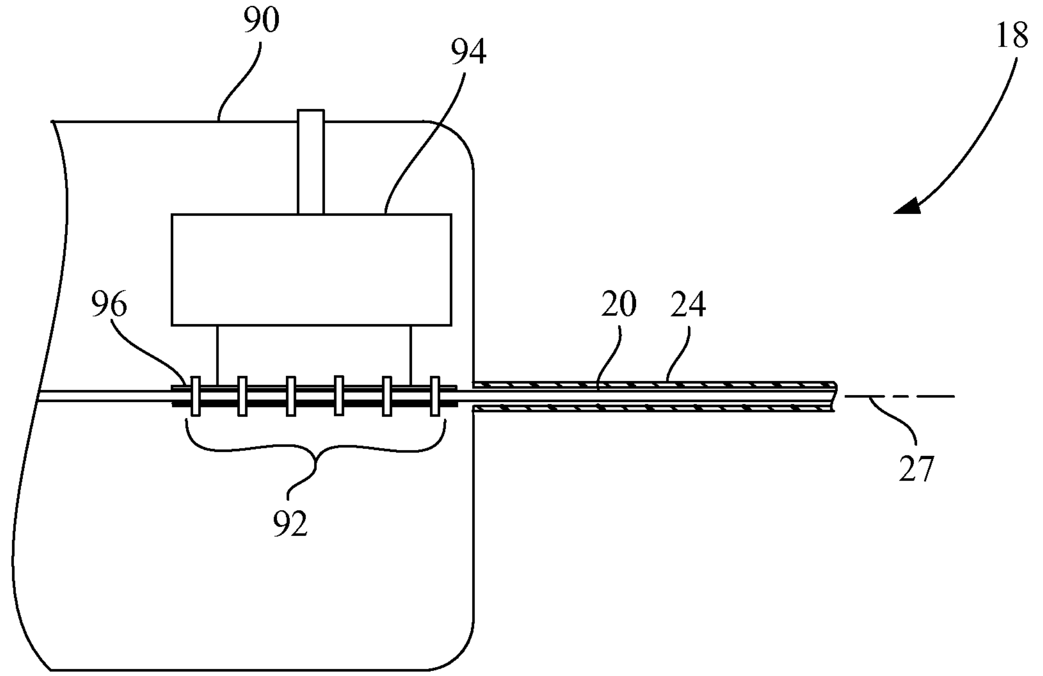

Fig. 8A

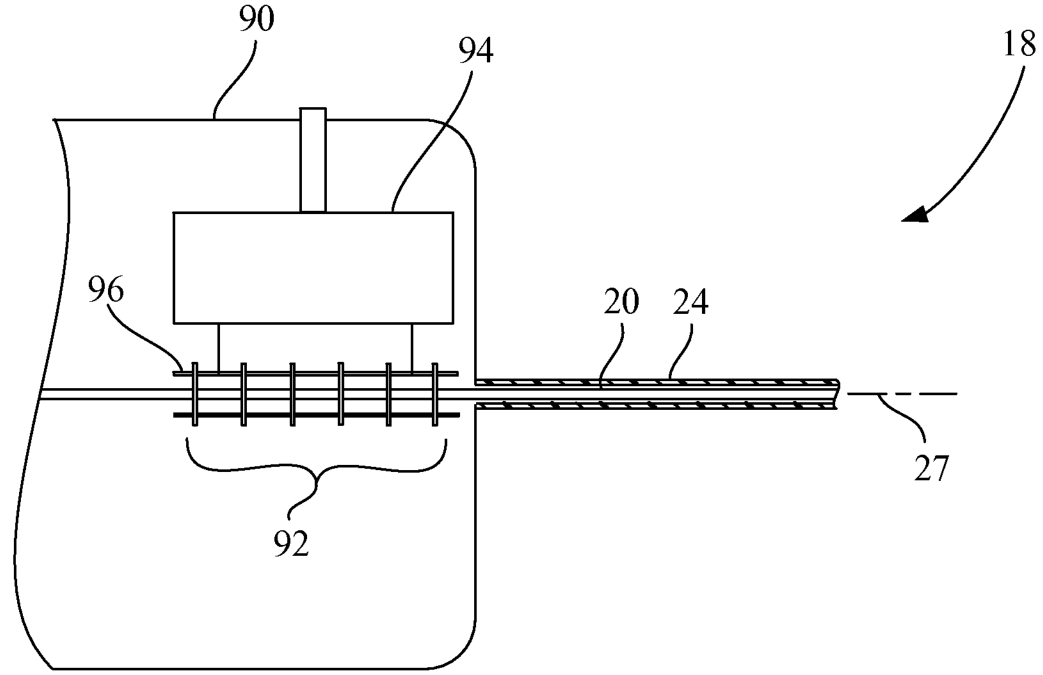

Fig. 8B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/024883

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22
ADD. A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92/11815 A2 (BAXTER INT [US]; SONICSTAR INTERNATIONAL LTD [US]; SIEGEL ROBERT J [US) 23 July 1992 (1992-07-23) figures 1, 13a, 13b page 8, line 6 - line 10 page 13, line 14 - page 14, line 12 page 20, line 23 - page 21, line 4 -----	1-5,9, 14-18,26
X	WO 01/24716 A1 (OMNISONICS MEDICAL TECH [US]) 12 April 2001 (2001-04-12) figure 6 page 7 - page 8 page 12 -----	1,3-5,9, 14-17,26

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 May 2015	12/08/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Emirdag, Eda

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/096061 A1 (OMNISONICS MEDICAL TECH [US]; RABINER ROBERT A [US]; HARE BRADLEY A [U) 11 November 2004 (2004-11-11) figures 5, 6 page 16, line 8 - page 18, line 11 -----	1,3-5,9, 14-17,26
A	US 2008/108902 A1 (NITA HENRY [US] ET AL) 8 May 2008 (2008-05-08) figures 2-5 paragraph [0030] - paragraph [0037] -----	1-5,9, 14-18,26
A	US 2013/253387 A1 (BONUTTI PETER M [US] ET AL) 26 September 2013 (2013-09-26) figures 8-10 paragraph [0190] paragraph [0208] - paragraph [0209] -----	1-5,9, 14-18,26

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/024883

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 9211815	A2	23-07-1992	CA	2099011	C	28-03-2000
			DE	69231357	D1	21-09-2000
			DE	69231357	T2	22-02-2001
			DE	69232059	D1	18-10-2001
			DE	69232059	T2	13-06-2002
			EP	0566656	A1	27-10-1993
			EP	0835644	A2	15-04-1998
			JP	H06507081	A	11-08-1994
			US	5304115	A	19-04-1994
			US	5326342	A	05-07-1994
			US	5397301	A	14-03-1995
			US	5540656	A	30-07-1996
			WO	9211815	A2	23-07-1992
WO 0124716	A1	12-04-2001	AT	286676	T	15-01-2005
			AU	770503	B2	26-02-2004
			AU	2004202221	A1	17-06-2004
			CA	2386052	A1	12-04-2001
			DE	60017386	D1	17-02-2005
			DE	60017386	T2	29-12-2005
			EP	1182976	A1	06-03-2002
			ES	2235951	T3	16-07-2005
			HK	1040605	A1	08-07-2005
			JP	4903961	B2	28-03-2012
			JP	2003527884	A	24-09-2003
			PT	1182976	E	29-04-2005
			US	6551337	B1	22-04-2003
			US	2003125645	A1	03-07-2003
			WO	0124716	A1	12-04-2001
WO 2004096061	A1	11-11-2004	AU	2003223347	A1	23-11-2004
			WO	2004096061	A1	11-11-2004
US 2008108902	A1	08-05-2008	EP	2079375	A2	22-07-2009
			JP	2010508966	A	25-03-2010
			JP	2013099561	A	23-05-2013
			US	2008108902	A1	08-05-2008
			US	2008108937	A1	08-05-2008
			US	2012130233	A1	24-05-2012
			WO	2008057264	A2	15-05-2008
US 2013253387	A1	26-09-2013	NONE			

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/024883

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-5, 9, 14-18, 26

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5, 9, 14-18, 26

   Displacement of the distal head

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2. claims: 6-8, 19-21

   Damping device

   ---

3. claims: 10-13, 22-25

   Transducer driving circuit
